

## **DETAILED ACTION**

### ***Status***

Applicant's preliminary amendment to the claims, filed 7/28/2006, is acknowledged. With entry of the amendment, claims 30-57 are pending and subject to restriction as follows.

### ***Election/Restrictions***

Applicant's reply to the Restriction Requirement mailed 2/24/2010 and election, with traverse, of  $\beta$ -D-oxy-LNA as the "sugar moiety which differs from ribose" and position 10 as the location of the sugar moiety that differs from ribose are acknowledged. However, the reply is not fully responsive to the requirement for the following reasons:

1. the response did not include an election of a single "non-RNA nucleobase" from claims 37-39;
2. the response did not include an election of an "at least one position" for the "non-RNA nucleobase" from the alternatives recited in claims 34-36;
3. the response did not include an election of an "at least one position" for the "internucleoside linkage group which differs from phosphate" from the alternatives recited in claims 50-52;
4. the response did not include an identification of the claims encompassing the elected species.

A telephone call to Attorney for Applicant, Colleen McKiernan, was made on or about 6/23/2010, but did not result in a completion of the election.

To be clear, the restriction requirement currently imposed is an election of species under PCT Rule 13.1 in accordance with 37 CFR 1.141-1.146. See MPEP 1893.03(d). The U.S.

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Examiner is not bound by any findings or lack thereof by the international examining authority.

Applicant's traversal on the grounds the claims do not lack unity of invention as demonstrated by the written opinion in PCT/DK2005/000062 is therefore not persuasive.

As provided in 37 CFR **1.475(a)**, an international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an international application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR **1.475(e)**.

As explained in the previous communication, mailed 2/24/2010, this application contains claims directed to more than one species of the claimed modified siRNA, generically defined by claim 30. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 and 37 CFR 1.475(a).

In one regard, the species of modified siRNAs, as generically recited by claim 30, differ one from the other by positioning of the "non-RNA nucleobase," "sugar moiety which differs from ribose," and internucleoside linkage group which differs from phosphate." These species are defined in the alternative by claims 34-36, 41-43, and 50-52. Additionally, Claim 55 defines a modified siRNA comprising a combination of sugar and nucleobase modifications at positions

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12 and 10, respectively. The special technical feature of each of these modified siRNAs is the inclusion of a modified sugar, nucleobase, and/or linkage in at least one of positions 8-14 relative to the 5' end of the sense strand. The special technical feature may be more particularly identified as the specific combination of any of these modifications at the same or different positions 8-14 of the sense strand, as, for example, defined by claim 55. Because these alternative species of siRNAs do not share the same special technical feature (i.e., are structurally distinct), the siRNAs as defined claims 34-36, 41-43, 50-52, and 55 lack unity of invention *a priori*. Applicant is therefore required to elect a single species of modified siRNA by specifying the positions for the “non-RNA nucleobase,” “sugar moiety which differs from ribose,” and “internucleoside linkage group which differs from phosphate” in the siRNA molecule for a provisional search and examination on the merits. It is noted that the response filed 5/7/2010 partially fulfills the requirement inasmuch as Applicant elected  $\beta$ -D-oxy-LNA as the “sugar moiety which differs from ribose” and position 10 as the location of the sugar moiety that differs from ribose. This election fulfills the requirement with regard to claims 40-48, but does not respond to the requirement as applied to claims 34-36 and 50-52. It is clear that a single modified siRNA may comprise each of the types of modifications defined by claim 32 at the same or different positions. Applicant is further requested to identify the claims that read on the elected species.

In another regard, the species of modified siRNAs differ one from the other by 1) the particular type of “non-RNA nucleobase,” defined in the alternative by claims 37-39; 2) by the particular type “sugar moiety which differs from ribose,” defined in the alternative by claims 46-48; and 3) by the particular type of “internucleoside linkage group which differs from

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phosphate,” defined by claim 53. The special technical feature of these modified siRNAs is the inclusion of at least one of these particular types of modified sugars, nucleobases, and/or linkages in at least one of positions 8-14 relative to the 5' end of the sense strand. The special technical feature may be more particularly identified as the inclusion of at least one particular type of sugar, nucleobase, or linkage modification or a specific combination of any of these particular modifications at the same or different positions 8-14 of the sense strand. Because these alternative species of siRNAs do not share the same special technical feature (i.e., are structurally distinct), the siRNAs differing by the type of sugar, base, or linkage modification lack unity of invention *a priori*. Applicant is therefore required to make a provisional election of a single type of nucleobase modification from claim 37-39, a single type of sugar modification from claims 46-48, and a single type of linkage modification, which alone and in combination define the species of siRNA to be examined in the first action on the merits. It is noted that currently only one type of linkage modification is recited. See claim 53. In the absence of any other alternatives this species of linkage would receive a search and examination on the merits and be considered the elected species by original presentation. It is also noted that applicant's election filed on 2/24/2010 is responsive the requirement as applied to claims 46-48.

Accordingly, outstanding elections are required in claims 37-39. The reply must also identify the claims readable on the elected species, including any claims subsequently added.

Accordingly, Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently

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added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: Claim 30.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment.

EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/  
Primary Examiner, Art Unit 1635  
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